

SUPPORTING STATEMENT

Suggested Documentation for Demonstrating Compliance with the Channels of Trade Provision for Foods with Vinclozolin Residues

A. Justification

1. Circumstances that make the collection of information necessary:

On August 3, 1996, the Food Quality and Protection Act (FQPA) was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. In accordance with the FQPA, the Environmental Protection Agency (EPA), the agency responsible for regulating the use of pesticides (under FIFRA) and establishing tolerances for residues of pesticide chemicals in food commodities (under the FFDCA), is in the process of reassessing the pesticide tolerances and exemptions that were in effect when the law was signed.

As part of the tolerance reassessment process mandated by the FQPA, in a cancellation order published in the **Federal Register** of November 4, 1998 (63FR59557), EPA cancelled, effective on the same date, several registered food uses for the pesticide vinclozolin. This action was precipitated by EPA's determination that the dietary risks from exposure to vinclozolin exceeded the safety standard under the FFDCA. Under the terms of the cancellation, application of the pesticide on the crops specified became unlawful after January 30, 2000.

Under section 408 (1) (2) of the FFDCA (21 U.S.C. 346a (1) (2)), (Attachment 1) when the registration for a pesticide is canceled or modified due in whole or in part to dietary risks posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

Since the registration for certain uses was canceled on November 4, 1998 and January 30, 2000 was the last date application of the pesticide on the crops specified as lawful, the tolerance is mandated by law (§408 (1) (2) of the FFDCA) to be revoked within 180 days of the latter date- January 30, 2000. FDA enforcement of the revoked tolerance must also begin at that time, since FDA is charged with enforcing the pesticide tolerances set by EPA for food commodities.

However, due to the residue dissipation rates of vinclozolin and the impact of food processing and storage, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the

tolerance revocation takes effect. For example, vinclozolin residues are expected to remain in frozen foods indefinitely.

FDA would normally deem a food found to contain a pesticide residue in excess of its set tolerance to be in violation of the law by virtue of it bearing an illegal pesticide residue, and the food would be subject to FDA enforcement action as an “adulterated” food. However, the channels of trade provision of the FQPA addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA (§408 (1) (5) of the FFDCA).

The information collection proposed in the draft guidance is necessary for FDA to determine whether or not food commodities found to contain vinclozolin after the tolerance for the pesticide in those particular commodities has been revoked, are in compliance with the channels of trade provision.

Examples of the information collected may include documentation associated with packing codes, batch records, and inventory records.

2. How, by whom, and for what purpose the information is to be used:

The information collected will be used to determine whether or not commodities found to contain vinclozolin after the tolerance for the pesticide in those particular commodities has been revoked, are in compliance with the channels of trade provision (§408 (1) (5) of the FFDCA). Such information will be collected by field personnel during the course of or in follow-up to inspections, investigations, and/or sample collections.

3. Use of technological techniques or other forms of information technology:

The collection of information does not involve the additional use of automated, electronic, mechanical, other technological collection techniques, or other forms of information technology. A route of electronic submission of this information has not been determined, but would be considered if proposed.

4. Efforts to identify duplication:

The information need only be collected should a potential violation be identified (i.e., a sample is found to contain an illegal pesticide residue). The documentation suggested in the draft guidance for demonstrating compliance with the channels of trade provision serves as another option provided to industry with regard to what type of information may be submitted to FDA should a potentially-violative sample be identified.

5. Impact on small businesses or other small entities:

The information collection does not have a significant economic impact on small businesses or other small entities.

6. Consequences if the collection is not conducted or is conducted less frequently:

If the collection is not conducted or is conducted less frequently, FDA will not be fulfilling its statutorily-mandated requirement (§408 (l) (5) of the FFDCA) to provide firms whose food product(s) are found to contain illegal pesticide residues an opportunity to demonstrate compliance of the product(s) with the channels of trade provision.

7. Special circumstances:

If, for some reason, samples are collected from a firm on a more-than-quarterly basis and these samples are found to be potentially violative, the firm may wish to report information with regard to demonstrating compliance of such commodities with the channels of trade provision. This would result in a firm reporting on more than a quarterly basis.

In addition, since vinclozolin residues are expected to remain in processed and frozen food commodities indefinitely, and processed and frozen foods are expected to remain in the channels of trade for up to four years after harvesting, firms dealing with processed and frozen foods which may be found to contain vinclozolin residues after the tolerance has been revoked, may wish to maintain records relating to the information collection for at least four years to ensure compliance with the provision may be demonstrated should a residue be identified.

8. Publication in the Federal Register:

A copy of the **Federal Register** notice published on July 10, 2001 (66 FR 35990) (Attachment 2) announced the availability of the draft guidance document proposing the channels of trade policy for commodities with vinclozolin residues. No comments were received.

9. Payment or gifts to respondents:

No decision has been made to provide any payment or gifts to respondents.

10. Assurance of confidentiality:

All information obtained by the agency will be reviewed in accordance with the guidelines set forth in the FDA Freedom of Information Regulations (21 CFR Part 20).

11. Questions of a sensitive nature:

This information collection does not contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Hour burden for the collection of information:

The likely respondents to this collection of information are firms in the produce and food-processing industries who handle food products that may contain residues of vinclozolin after the tolerances for this pesticide have been revoked.

Estimated Annual Reporting Burden

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
307	1	307	3	921

Estimated annual reporting burden was determined using the total number of samples historically tested for vinclozolin and the number of samples which historically contained vinclozolin residues. These numbers established a rate of samples expected to have vinclozolin residue. This rate, when applied to the number of potentially affected establishments, was used to calculate the number of expected respondents.

Considering the variation in and effects of food handling, particularly with regard to the time between pesticide application and processing/freezing, FDA estimated that potentially 1.36% of domestic and 2.72% of imported food products sampled may contain vinclozolin residues, and therefore, the responsible party, under the approach set forth in the draft guidance, would be subject to the reporting requirement since it would be the burden of the responsible party to demonstrate that the food found to contain vinclozolin residues within the former tolerance was packed or processed on or before July 1, 2000.

Estimated Annual Recordkeeping Burden

No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
31	1	31	16	496

In determining the Estimated Annual Recordkeeping Burden, FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms which may not currently be maintaining this documentation, to develop and maintain (or maintain access to) documentation such as batch records and inventory records.

Costs to Respondents

Annualized cost to respondents for the reporting burden determined (921 hours) was estimated to be \$9210. This was determined using an average wage of \$10/hr for employees involved in reporting information used to demonstrate compliance with the channels of trade provision.

Annualized cost to respondents for the recordkeeping burden determined (496 hours) was estimated to be \$4960. This was determined using an average wage of \$10/hr for employees involved in the recordkeeping aspect of information used to demonstrate compliance with the channels of trade provision.

13. Annual cost burden to respondents or recordkeepers:

For firms that do not maintain (or maintain access to) documentation such as batch records and inventory records as part of their normal manufacturing operations, it was estimated that with \$500 or less, the necessary software and/or hard copy filing systems could be obtained to implement a system.

14. Annualized cost to the federal government:

This information will be collected in response to potentially-violative samples of commodities found to contain vinclozolin residues. Firms responsible for such samples generally submit, or have an opportunity to submit, information in their defense to the agency. This information provides firms another option with regard to what type of information may be submitted should a potentially-violative sample be identified, and will therefore not require additional FDA personnel or funding to review.

15. Reasons for program changes and adjustments:

This is a new collection; there were therefore no program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

16. Plans for tabulation and publication of information whose results will be published:

The results of this information collection will not be published.

17. Reasons why display would be inappropriate if seeking not to display OMB-approval date:

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

18. Reasoning for exceptions to the certification statement:

No exceptions to the certification statement were identified.

B. Collection of Information Employing Statistical Methods

The collection of information proposed in this draft guidance does not employ statistical methods.